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EXAMINER

BASQUILL, SEAN M

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/544,154
Filing Date: August 01, 2005
Appellant(s): SMITH, FRANCIS X.

Jason Womer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3 December 2010 appealing from the Office action mailed 3 December 2009.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the Brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings aside from those listed by the Appellants, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-20 are rejected and pending appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

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(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,817,277	Mowrey-McKee	10-1998
5,741,817	Chowhan	04-1998
5,620,970	Han	04-1997

U.S. Application 11/613,061

U.S. Application 10/544,149

U.S. Application 11/613,050

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 (hereinafter “Mowrey-McKee”), in view of U.S. Patent 5,741,817 (hereinafter “Chowhan”).

Mowrey-McKee describes methods and compositions for the disinfection of contact lenses. (Abs.). The compositions to be used in the method of disinfecting contain tromethamine, or TRIS, in a concentration of between 0.5-1.2% (C.4-9, Examples 1A, 1B, 2a-i, 3C, 4, and 5), microbicides such as hydrogen peroxide in concentrations ranging between 50-200 ppm (0.005-0.02%) or PHMB in concentrations such as 0.0001% (1 ppm) (C.3, L.5-9; C.7-8, Examples 3C & 4), chelating agents such as EDTA (C.2, L.36-59), buffered to a pH of between 6-8, preferably 6.8-7.8 or 7.3-7.7 (C.2, L.60-67), tonicity adjusters to adjust the composition's osmolality to approximately 240-310 mOsm/kg (C.3, L.20-32), such as sodium chloride in concentrations ranging between 0.3-0.44% (C.4-8, Examples 1A, 1B, 3C, 4, and 5), and surfactants in

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concentrations ranging between 0.0001-20%, preferably 0.005-5%, more preferably between 0.025-1% (C.3, L.33-47).

Mowrey-McKee does not describe including L-histidine in the composition, nor is a single specific embodiment encompassing all of the above components in the above referenced quantities described.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of the disclosed TRIS buffer, microbicides including PHMB and hydrogen peroxide, EDTA, sodium chloride, and surfactants in the quantities described above from within the disclosure of Mowrey-McKee, to arrive at the instantly claimed ophthalmic compositions,

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aside from the histidine component of the instant claims, “yielding no more than one would expect from such an arrangement.”

Concerning the claimed ranges of components of the instant application, while the prior art does not disclose the exact claimed values, the ranges of the claimed composition components described in Mowrey-McKee overlap with or touch upon those of the instant claims. In such instances even a slight overlap in range establishes a prima facie case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

It would have been prima facie obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

2. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Chowhan as applied to claims 1-3 and 5-20 above, and further in view of U.S. Patent 5,620,970 (hereinafter "Han").

Mowrey-McKee as modified by Chowhan describes compositions and methods of disinfecting contact lenses as detailed above, but does not specifically describe hydroxyethoxylated castor oil among the surfactants which may be used in the composition and methods as claimed.

Han indicates that polyethoxylated castor oils such as CREMPHOR EL are known to be useful as surfactants in topical ophthalmic compositions. (C.2, L.1-15).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have substituted the surfactant CREMOPHOR EL of Han for the surfactants of Mowrey-McKee as modified by Chowhan to provide a topical ophthalmic solution for the disinfection of contact lenses. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because they would have recognized that the CREMOPHOR ophthalmic surfactant of Han was a suitable replacement for, or equivalent of, the ophthalmic surfactants of Mowrey-McKee as modified by Chowhan. Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. MPEP 2144.07. Additionally, it is prima facie obvious to substitute one equivalent component for another, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very

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same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

3. Claims 1-14, 16, 18-20 are provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 2, 4, 7, 8, and 10-19 of copending Application No. 11/613,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genera described in the '061 application overlap with the genera claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-20 are provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-5, 7-13 of copending Application No. 10/544,149 in view of U.S. Patent 5,741,817 ("Chowhan").

Claims 1-5 and 7-13 of the '149 application describe ophthalmic solutions comprising hydrogen peroxide, cationic polymeric preservatives, buffers, surfactants, germicides, and chelating agents as put forth in the instant claims, but does not include L-histidine.

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

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It would have been prima facie obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of the '149 application. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

This is a provisional obviousness-type double patenting rejection.

5. Claims 1, 3-12 are provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-5 and 8 of copending Application No. 11/613,050 in view of U.S. Patent 5,741,817 ("Chowhan").

Claims 1-5 and 8 of the '050 application describe ophthalmic compositions comprising hydrogen peroxide producing agents, cationic polymeric preservatives, buffers and surfactants of the instant invention, but does not specify the inclusion of L-histidine.

Chowhan describes the use of low molecular weight amino acids in ophthalmic compositions to increase the efficacy of antimicrobial preservatives, especially when used for the rinsing and storage of contact lenses. (Abs.; C.1, L.45-60). The useful amino acids therein

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described include histidine, which Chowhan indicates may be used in concentrations ranging from about 0.01-7%. (C.2, L.1-20).

It would have been prima facie obvious to one having ordinary skill in the art to have incorporated the preservative enhancing amino acids including histidine of Chowhan into the ophthalmic compositions of the '050 application. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because of the explicit teaching of Chowhan that the inclusion of low molecular weight amino acids improves the efficacy of antimicrobial preservatives in ophthalmic solutions, particularly those used for the rinsing and storage of contact lenses. Generally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

This is a provisional obviousness-type double patenting rejection.

(10) Response to Argument

Appellants sole avenue of rebutting the examiner's prima facie case of obviousness lies in the argument that combining EDTA with the compositions claimed by Chowhan would frustrate the purpose of the Chowhan compositions, thereby rendering the reference unsatisfactory for its unintended purpose. Appellants argue that because Chowhan indicates that "some scientific studies have indicated that EDTA may damage corneal cells," and have elected to claim as their invention a topical ophthalmic compositions which does not contain EDTA, that this amounts to a teaching away from the use of amino acids such as histidine in

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ophthalmic compositions which contain EDTA. This is not found persuasive for three reasons: the so-called “warning” against the use of EDTA is unconvincing, EDTA is well-known and generally recognized as safe, effective and useful in topical ophthalmic compositions, and taken as a whole the state of the art fails to teach away from the combination of EDTA and histidine.

First, Chowhan's warning concerning the potential hazards of EDTA use in ophthalmic compositions is simply that – a warning of potential hazards and not an absolute proscription on its use. Any action carries with it the potential for deleterious side effects and unintended consequences; it is for the skilled artisan to weigh and measure these potential side effects against the therapeutic benefit to be expected from such a use and decide as a learned intermediary the most prudent course of action. Second, Chowhan affirmatively indicates that EDTA has “been widely used for many years in ophthalmic products, particularly products for treating contact lenses.” (C.1, L.20-22). The uses to which EDTA has been put in such compositions varies widely, but in particular it is known “for its supplemental antimicrobial activity and as a chelating agent...[which] enhances the antimicrobial efficiency of chemical preservatives contained in such compositions.” (C.1, L.24-28). In sum, Chowhan teaches both the use of amino acids such as histidine, as well as EDTA, as components of ophthalmic compositions which are each individually known to enhance the antimicrobial efficiency of chemical preservatives used therein. Many compounds generally recognized as safe and effective come with what amounts to little more than either boilerplate warnings designed to satisfy legal counsel's desire to avoid product liability suits, or mere puffery aimed at improving the appearance of one's own product; the examiner considers the warning contained in Chowhan, such as it is, as falling within either or both of the aforementioned categories.

Thirdly, given the above teachings from within Chowhan, which the examiner asserts represents the state of the art at the time of the filing of the instant application, appellants have failed to convincingly demonstrate that the art teaches away from the combination of EDTA and amino acids such as histidine in ophthalmic compositions. To properly argue that prior art is either incapable of being combined or teaches away from the combination suggested by the examiner, appellants must either indicate how the claimed combination would either change the principle of operation of the primary reference or render it inoperable for its intended purpose, MPEP § 2145(III), or “criticize, discredit, or otherwise discourage the solution claimed.” MPEP § 2145(X)(D), citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Here, appellants have offered no evidence to establish either that the combination suggested by the examiner would render the primary reference inoperable for its intended purpose or presented evidence to establish that the combination claimed has been criticized, discredited, or otherwise discouraged. See MPEP § 2145(I) (indicating attorney argument does not replace evidence where evidence is required). Indeed, looking to in particular Column 4, Line 65 through Column 5, Line 38 (example 4), the disclosure of Chowhan itself clearly states that EDTA cannot simply be eliminated from topical ophthalmic compositions while USP preservative efficacy is maintained; some antimicrobial agent or combination of agents must be utilized. As described in greater detail above, the examiner asserts that the combination of EDTA and amino acids in ophthalmic compositions may actually be encouraged by the disclosure of Chowhan, notwithstanding the preferred embodiments of the Chowhan invention which do not contain EDTA. See MPEP § 2123 (indicating that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or the disclosure of nonpreferred embodiments). Where a prior

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art disclosure provides teachings that would suggest to the artisan possessing ordinary skill a rationale for combining two components individually taught in the art as useful for the same purpose, the combination is prima facie obvious; the idea for combining them flows logically from their having been individually taught in the prior art. MPEP § 2144.06. Here, Chowhan indicates that both EDTA and amino acids such as histidine are useful for increasing the efficacy of antimicrobial components of ophthalmic compositions. This not only suggests the suitability of each enhancer either alone or in combination, but would also reasonably suggest that a similar enhancement of antimicrobial effect may be achieved by using less of either individual enhancer in such a combination, when compared with the amounts needed to achieve the same enhancement effect using either enhancer alone, thereby reducing the probability of experiencing side effects resulting from the use of either agent in therapeutically effective amounts alone.

For at least the above reasons, appellants rebuttal arguments are deemed unpersuasive and, until sufficient evidence of secondary indicia of nonobviousness commensurate in scope with the invention as claimed is provided, the obviousness rejection stands.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/Sean Basquill/

Examiner, Art Unit 1613

Conferees:

/Brian-Yong S Kwon/

Supervisory Patent Examiner, Art Unit 1613

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